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K961610

510(k) Summary
R&D Systems' Whole Blood Flow Control

Date of Summary: April 25, 1996
Company Name: R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
Contact name: Kenneth T. Edds, Ph.D.
612-379-2956, FAX 612-379-6580
Classification name: automated differential cell counter
Product name: R&D Whole Blood Flow Control
CFR section: 864.5220
Device Class: Class II

Device to which substantial equivalence is claimed:
CD Chex, manufactured by Streck Laboratories, 14306 Industrial Rd. Omaha, NE 68144.
510(k) number: K920997

The product is an assay control mixture for flow cytometric determinations of leukocyte subsets present in whole blood samples. R&D Systems' Whole Blood Flow Control is composed of human leukocytes and erythrocytes in a stabilizing medium.

Intended use: R&D Systems' Whole Blood Flow Control (WBFC) is a stabilized preparation of human peripheral leukocytes and erythrocytes to be used as a control in the complete immunophenotyping process which includes: antibody staining, RBC lysis, instrument set-up and instrument performance.

R&D Systems' Whole Blood Flow Control has an intended use that is similar to the predicate device but, in addition, includes the lysis of red blood cells in the control protocol. The technologies of the two devices are similar.

Nonclinical testing centered on the performance attributes of stability and precision. WBFC passed the acceptance criteria of remaining within the assay range over the life of the product. WBFC also demonstrated precision as indicated by the small standard deviations and low CVs obtained during the testing. WBFC was also compared, in terms of precision, to freshly drawn whole blood and found to exhibit similar reproducibility of performance. Expiration dating has been established as 28 days closed vial and 7 days open vial when stored at 2-8°C and handled according to instructions for use.